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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,166	12/08/2000	Richard W. Compans	96-99	2363

23713 7590 08/27/2003

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SUITE 201
BOULDER, CO 80303

EXAMINER
LI, BAO Q

ART UNIT	PAPER NUMBER
1648	25

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,166	COMPANS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/3/03

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *,62,64-65 and 67-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62,64-65 and 67-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

This is a response to the amendment, paper No. 24, filed 07/03/03. Claims 63, and 66 have been canceled. Claims 62 and 64-65 have been amended. New claim 70 has been added. Claims 62, 64-65, and 67-70 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. Claims 62, 64-65, 67-68 is still are rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, because the specification, while being enabling for using a formalin inactivated influenza virus P8/5 to induce a serum immune response in a CD4 deficient mouse model, does not reasonably provide enablement for using any or all inactivated of attenuated virus to induce a serum immune response in a CD4 deficient animal and human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

2. In response Office Action, Applicants traverse the rejection by amending claim 26 as a method of using the composition as an inactivated or attenuated virus to induce a humoral immune response in CD4+ T cell deficient subject. Applicants submitted that, accordingly, the rejection should be withdrawn.

3. Applicants' argument has been respectfully considered; however, it is not found persuasive because the specification, while being enabling for using a formalin inactivated influenza virus P8/5 to induce a serum immune response in a CD4 deficient mouse model, does not reasonably provide enablement for using any or all inactivated of attenuated virus to induce a serum immune response in a CD4 deficient animal and human based on the disclosure of the specification. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

4. Claims 62, 64-65, 67, 68 and 70 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action, as being anticipated by Compans et al. (US patent No. 4,790,987A).

5. Applicants ague that Compans et al. Teach that a vaccine composition containing virus derived from intact virus and claim 62 has amend to an immunogenic composition comprising an inactive or attenuated virus. Furthermore, they do not teach to use the said component for inducing an immune response in a subject deficient in CD4+ T cells. Therefore, it does not teach each element of claimed invention.

6. Applicants' argument has been respectfully considered; however, it is not found persuasive because one of the compositions used in the vaccination procedure by Compans et al. is disclosed as a formalin-inactivated influenza virus (lines 52 on col. 11 through lines 40 on col. 12).

7. Regarding to the subject is deficient with CD4+ T cells; this limitation does not change the step of manipulating the use of the structural and functional identical composition. Because no matter a composition is used in which subject, the characteristic of the composition does not change due to the condition of the subject; the invention is not a new use of a process. Therefore, it is still anticipated by the cited reference.

8. Claims 62 and 64-65, 67-68 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Murphy et al. (Vaccine 1990, Vol. 8, pp. 497-502).

9. Applicants ague that Murphy et al. teach that a method for immunization with an inactivated RSV or purified F glycoprotein in rat and claim 62 has amend to an immunogenic composition comprising an inactive or attenuated virus. Furthermore, they do not teach to use the said component for inducing an immune response in a subject deficient in CD4+ T cells. Therefore, it does not teach each element of claimed invention. Therefore, the cited prior art does not teach the claimed invention.

10. Applicants' argument has been respectfully considered; however, it is not found persuasive because Murphy et al. teach a method for immunization animal rats by using a

composition with a formalin-inactivated respiratory syncytial virus (RSV) (See section of materials and methods on page 498), in which the RSV is a formalin inactivated envelope virus and rat is an animal.

11. Regarding to the subject is deficient with CD4+ T cells; this limitation does not change the step of manipulating the use of the structural and functional identical composition. Because no matter a composition is used in which subject, the characteristic of the composition does not change due to the condition of the subject; the invention is not a new use of a process. Therefore, it is still anticipated by the cited reference.

12. Claims 62, 64-65 and 68 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Muster et al. (J. Virol. 1994, Vol. 68, pp. 4031-4034).

13. Applicants argue that Muster et al. describe an immunization study by using a chimeric influenza virus containing a HIV peptide epitope in mice and claim 26 has been amended to a inactivated or attenuated virus. Furthermore, they do not teach to use the said component for inducing an immune response in a subject deficient in CD4+ T cells. Therefore, it does not teach each element of claimed invention

14. Applicants' argument has been respectfully considered; however, it is not found persuasive because the chimeric influenza virus is attenuated virus as compared to the wild type virus having less or loosing the potent pathogenic effect. The mice are animals.

15. Regarding to the subject is deficient with CD4+ T cells, this limitation does not change the step of manipulating the use of the same structurally and functionally composition. Because no matter a composition is used in which subject, the characteristics of the composition does not change due to the condition of the subject, and the invention is not a new use of a process. Therefore, it is still anticipated by the cited reference.

16. Claims 62, 64-65 and 68 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action, as being anticipated by Li et al. (J. Virol. 1993, Vol. 67, pp. 6659-6666).

17. Applicants argue that Li et al. describes the use of chimeric influenza virus expressing an epitope of HIV to induce an immune response, and they do not teach to use the said component for inducing an immune response in a subject deficient in CD4+ T cells.

18. Applicants' argument has been respectfully considered; however, it is not found persuasive because the chimeric influenza virus is an attenuated virus compared to the wild-type influenza virus for losing the potent pathogenic effect.

19. Regarding to the subject is deficient with CD4+ T cells; this limitation does not change the step of manipulating the use of the structural and functional identical composition. Because no matter a composition is used in which subject, the characteristic of the composition does not change due to the condition of the subject; the invention is not a new use of a process. Therefore, it is still anticipated by the cited reference.

20. Claims 62, 64-65, 68 an 70 are rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Pales et al. (J. Inf. Dis. 1997, Vol. 176 (Suppl 1), pp. S45-S49).

21. Applicants argue that Pales et al. describes the use of recombinant influenza virus vector for expressing an epitope of HIV to induce an immune response, and they do not teach to use the said component for inducing an immune response in a subject deficient in CD4+ T cells.

22. Applicants' argument has been respectfully considered; however, it is not found persuasive because the chimeric influenza viral vector is an attenuated virus compared to the wild-type influenza virus for losing the potent pathogenic effect.

23. Regarding to the subject is deficient with CD4+ T cells; this limitation does not change the step of manipulating the use of the structural and functional identical composition. Because no matter a composition is used in which subject, the characteristic of the composition does not change due to the condition of the subject; the invention is not a new use of a process. Therefore, it is still anticipated by the cited reference.

24. Claims 62, 64-65, 67-68 and 70 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Budowsky et al. (Vaccine 1993, Vol. 11, pp. 343-348).

25. Applicants acknowledged that Budowsky et al. teach a method for immunization animal mice with a beta-propiolactone (PL) -inactivated influenza virus. However, Applicants argue that Budowsky et al. do not teach to use the said component for inducing an immune response in a subject deficient in CD4+ T cells.

26. Applicants' argument has been respectfully considered; however, it is not found persuasive because Budowsky et al. teach a method for immunization animal mice with a beta-propiolactone (PL) -inactivated influenza virus.

27. Regarding to the subject is deficient with CD4+ T cells; this limitation does not change the step of manipulating the use of the structural and functional identical composition. Because no matter a composition is used in which subject, the characteristic of the composition does not change due to the condition of the subject; the invention is not a new use of a process. Therefore, it is still anticipated by the cited reference.

Conclusion

No claims are allowed.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

Art Unit 1648

August 18, 2003

James C. Housel
JAMES HOUSEL 8/25/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600